



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2003

Mr. Thomas R. Gunerman
President
Intersurgical, Inc.
417 Electronics Parkway
Liverpool, NY 13088

Re: K024270

Trade/Device Name: Clear-Therm 3 HMEF (PN 1541), Clear-Therm HMEF w/Superset (PN 1541-T), Clear-Therm HMEF w/Flextube (PN 1541-F), Clear-Guard 3 Filter (PN 1544), Clear-Guard 3 w/Superset (PN 1544-T), and Clear-Guard 3 w/Flextube (PN 1544-F)

Regulation Number: 21 CFR 868.5260

Regulation Name: Breathing Circuit Bacterial Filter

Regulatory Class: II

Product Code: CAH

Dated: March 24, 2003

Received: March 27, 2003

Dear Mr. Gunerman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

JUN 24 2003

Appendix J. Indication For Use

510(k) Number (if known): K024270

Device Name: 1544 Clear-Guard 3 Filter with CO2 Monitoring Port
1544-T Clear-Guard 3 with Superset catheter mount
1544-F Clear-Guard 3 with flexible catheter mount
1541 Clear-Therm 3 HMEF with CO2 Monitoring Port
1541-T Clear-Therm 3 HMEF with Superset catheter mount
1541-F Clear-Therm 3 HMEF with flexible catheter mount

Indications For Use:

1544, 1544-T & 1544-F: For use at the equipment or patient connection. Designed to reduce bacterial/viral transmission to and from patient, equipment and environment. **CAUTIONS:** When used in the exhalation limb in conjunction with a water bath humidifier, a water trap should be placed between the filter and the patient;

1541, 1541-T & 1541-F: For use at the patient connection. Designed to reduce bacterial/viral transmission and to reduce the loss of patient heat and humidity. **CAUTIONS:** This product is not suitable for patients with thick or copious secretions; Do not use this product in conjunction with other humidification sources.

1544, 1544-T, 1544-F, 1541, 1541-T, 1541-F: ISO connections: When assembling any connections use a push and twist action to ensure a secure fit. Single patient use. Non conductive. Non sterile. Do not autoclave. **CAUTIONS:** Never position any filter on the inspiratory limb downstream of a water bath humidifier; Do not use this product between the patient and a source of nebulized drugs; When nebulized drugs are administered, resistance should be monitored and the product should be exchanged following standard hospital procedure; All ports should remain capped when not in use; Replace every 24 hours or more frequently if visible deterioration is observed, following standard hospital procedure; Federal law restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K024270

Prescription Use X
(Per 21 CFR 801.109)

or Over-The-Counter Use _____

(Optional Format 1-2-96)